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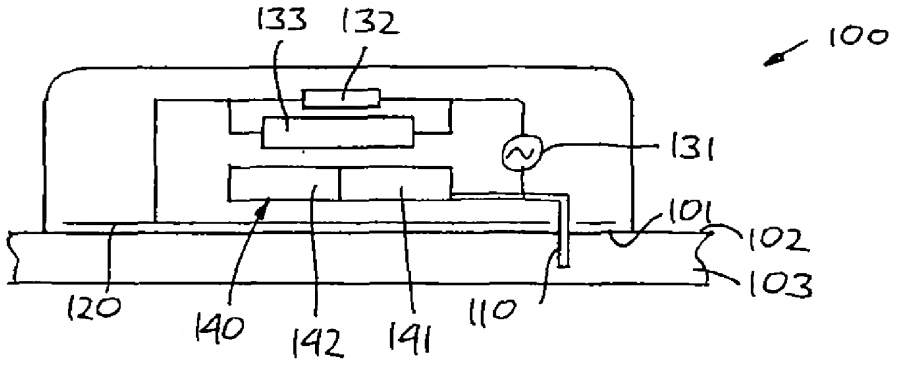
(54) Title: SENSOR SYSTEM AND METHOD FOR DETECTING PROBLEMS WITH MOUNTING OF SKIN MOUNTABLE MEDICAL DEVICES



(57) Abstract: The invention relates to skin mountable medical devices adapted to ensure that the device or components thereof are properly in place with respect to the patient's body. In a specific aspect a medical device is provided comprising a mounting surface adapted for application to a skin surface of the subject, a transcutaneous device adapted to be arranged subcutaneously in a subject, and sensor means adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject. The device further comprises circuitry for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected, and wherein the sensor means comprises first and second capacitor means.

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SENSOR SYSTEM AND METHOD FOR DETECTING PROBLEMS WITH MOUNTING OF SKIN MOUNTABLE MEDICAL DEVICES

BACKGROUND OF THE INVENTION

The invention relates to skin mountable medical devices in general and in particular provides, among other things, systems and methods for ensuring that the device or components thereof are properly in place with respect to the patient's body.

BACKGROUND OF THE INVENTION

For many conditions, medical devices that are attached to the body of a patient can greatly assist in treatment and/or diagnosis. For example, insulin pumps are becoming smaller, have remote controls, and can be worn directly on the body, thus eliminating the need for long catheters and direct pump access. A major concern with many skin mountable devices is ensuring that the device or a component of the device has not lost attachment with a skin surface or that a probe, needle, tube, cannula, etc. is no longer properly inserted or positioned on the skin of a patient., *i.e.* has become disengaged or that a reaction is occurring at the site wear a device is mounted to the skin of a patient

For wearable medical devices disengagement from the skin is a general concern, but for life saving wearable devices, such as insulin pumps or other medication delivery systems, disengagement can be life threatening. And often the patient is not aware that the device has become disengaged or that a portion has moved out position by a sufficient amount to make the device ineffective.

In addition to detecting disengagement of pumps, devices, or transcutaneous devices, it is also desirable to detect local inflammation/infection at the mounting site, particularly at the insertion site of a transcutaneous device, such as a needle or cannula. This is important because inflammation, among other things, may adversely affect operation of the device, can be a sign of serious problems, and causes discomfort for the user. Early detections can improve the quality of treatment by, among other things, resulting in termination of a specific treatment regimen or treatment with a specific apparatus, thereby minimizing tissue injury, securing consistent treatment, and can help minimize cost of treatment by prolonging usage

of a system. Of course, in some cases merely knowing when to change an infuse set can greatly improve conditions for a patient.

When inflammation occurs, it is usually accompanied by detectable local changes in biological parameters. These properties include, chemical changes near insertion or trauma site, temperature rise, changes in optical properties (e.g. reddening), mechanical property changes, electrical property changes, increased neural activity, changes in acoustic properties or a combination hereof.

While many aspects of the present invention are useful with a number of medical devices, such as trans-dermal medication patches, medical sensors, conventional insulin delivery infuse sets, etc., it is particularly well-suited for use with wearable infusion pumps. Typically these pumps have some form of electronic control or a processor. The control units of these pumps can be readily adapted to monitor sensor systems that detect whether a portion of the pump is no longer properly positioned. Typically, at least several failure conditions can occur that should be brought to the attention of a patient: adhesive failure, or transcutaneous device disengagement. Of course, the present invention can be used to detect other problems, such as inflammation, and can be used with virtually any wearable device.

Soft cannulas are replacing rigid steel needles in many infusion and injection devices. These soft cannulas provide many advantages, (e.g. they are more comfortable, cause less reactions, and, in some cases, have better long term properties). Unfortunately, soft cannulas also have some drawbacks. For example, a soft cannula can become crimped and thus not properly deliver medication. Crimping and/or kinking is especially an issue with the insertion of soft cannulas and flexible catheters, especially those inserted at 90 degrees, and/or are of a length of 8mm or shorter. In addition to crimping problems, the soft cannula may be improperly inserted by not being fully extended into the proper skin region. As these cannulas are more comfortable for a patient, the patient may not feel that they have become crimped or otherwise not properly inserted.

Presently, to overcome these problems, the insertion site must be visible to allow the wearer to detect an incorrect insertion, or, in the case of insulin delivery devices, users must test blood sugar at certain intervals after inserting a new infusion set to detect if blood sugar is higher than expected.

Today, these problems require that users a) be able to see the insertion site and b) remember to test their blood sugar at approximately 3 hours after changing infusion sets and typically a couple of times per 24 hour. Thus, it would desirable to have a system that warns a patient of cannula failure so that the patient can correct this problem. Such a system and method of warning a patient is highly desirable in the case of devices that deliver life saving medications, such as insulin, or that monitor life threatening conditions. Additionally, it would be convenient to have a system that allows the cannula to be inserted while it is concealed from the view of the user.

SUMMARY OF THE INVENTION

The present invention may take the form of many embodiments. Those listed here are merely examples and are not in anyway to be construed as the only embodiments possible.

In general, a medical device is provided, comprising a skin mountable surface having an adhesive for mounting on a skin surface of a patient, a sensor that detects a property that can be indicative of a problematic condition relating to the interface of the device with the patient, and a circuit for sending a signal in response to a predetermined signal from the sensor.

Thus, in a first aspect of the invention a medical device is provided, comprising a mounting surface adapted for application to a skin surface of the subject, a transcutaneous device adapted to be arranged subcutaneously in a subject, and sensor means adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject. The device further comprises circuitry for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected, and wherein the sensor means comprises first and second capacitor means.

The transcutaneous device may be adapted to conduct an electric current (e.g. through the wall of a conduit, through a drug contained in the conduit, or through a metal conductor), the first capacitor means may be a capacitor plate associated with the mounting surface, and the second capacitor means may be established by the transcutaneous device when it is arranged in the subcutis of the subject, whereby a capacitor can be established between the capacitor plate and the subcutis area positioned there below. Alternatively, the first and second capacitor means are first and second capacitor plates associated with the mounting sur-

face, a capacitive circuit being established when the mounting surface is arranged on a skin surface.

In specific embodiments the device comprises a patch unit and a housing unit adapted to be coupled to each other, the patch unit comprising the mounting surface and the capacitor plate(s), and the housing unit comprising the circuitry, and wherein the circuitry may be coupled to the capacitor plate(s) by e.g. a capacitive coupling or a galvanic contact.

In a further embodiment of the present invention, a medical device is provided with a skin mounting surface. The surface may have a skin adhesive applied thereon, or a separate adhesive layer may be used. The adhesive or adhesive layer does not have to cover the entire skin mounting surface. A sensor system can be installed to determine when one portion of the skin mounting surface is sufficiently non-coplanar with another portion so as to indicate that there is at least a portion of the device that is no longer properly engaged with the patient.

One embodiment may employ one or more openings (including cut-away portions) in the skin mounting surface and a sensor that senses when portions of the skin mounting surface across an opening from each other are substantially non-coplanar. In a particular embodiment, the sensor comprises two electrical contacts that are mounted directly across the opening from each other. If it is desirable to detect that a needle or cannula is disengaged, the needle or cannula may be mounted thru a portion of the skin mounting surface. That portion can have a sensor that detects when that portion is no longer substantially co-planar with another portion of the skin mounting surface, thus indicating that the needle or cannula may be disengaged.

In another embodiment of the present invention, a transcutaneous device's position is monitored via one or more sensors relative to the skin mounting surface. By this arrangement it is possible to monitor whether a portion of the transcutaneous device or a member associated with the transcutaneous device moves relative to a portion of the skin mounting surface. If the movement is greater than a predetermined amount, the sensor or sensors can be designed to send a signal that movement indicative of disengagement has occurred.

Another embodiment of the present invention that is particularly useful with two-piece infusion pumps, or other multi-piece devices, also comprises a skin mountable surface, usually

on a first piece of the pump or device. This piece may have an adhesive on the skin mounting surface and may also have holes on the skin mounting surface. This piece is typically, but not necessarily, adhered to the skin first. A second piece of the pump or device is then attached to the first piece. By manufacturing the first piece with one or more openings or holes in the skin mounting surface, one or more sensors from the second piece can pass thru the holes and contact the skin. The sensors could be mechanical in nature and sense for example pressure, or they could sense skin properties such as impedance, temperature, etc. These sensors can be configured to detect when one portion of the skin mounting device is substantially non-coplanar with another portion or whether a particular sensor is not in sufficient contact with the skin so as to ensure that the device or a portion thereof is properly engaged with the patient.

Where multiple sensors are employed with the present invention, one way to determine whether the device is disengaged is to measure a skin property at each sensor and then to compare the properties. Assuming that the device is relatively small, the properties at any sensor within the area defined by the skin mounting surface should be approximately similar. And thus if difference larger than expected are encountered, this may be an indication of disengagement with the skin.

While mechanical sensors can be used, it may be desirable to use other sensor types, such as temperature, electrical, optical, etc. Where electrical sensors are used, one embodiment may have two electrical contacts and skin impedance between the contacts can be monitored. If impedance becomes too high, this might indicate disengagement. In a similar embodiment a delivery cannula or needle is used as one portion of the sensing system, for example as an electrical skin contact, and another portion is mounted elsewhere on the skin mountable surface. Skin properties (e.g. impedance, etc) between these two points can be measured and/or monitored for a change indicative of a loss of skin contact or disengagement from the body of the user. If an electrical conducting cannula is used or if the liquid to be infused is electrically conductive the cannula/infusion liquid may be used as sensor in it self, thus making a circuit like that depicted in figure 4 possible employing only one additional electrode.

In one embodiment the signal send by the device is acoustic, thus directly notifying the wearer of the device that corrective action has to be carried out. In another embodiment an electromagnetic signal is send to a control unit comprising means for alarming the wearer of

the device. In a yet another embodiment an electromagnetic signal is send from the device to a relay device. Upon receiving the alarm signal the relay device conveys the alarm to one or more further devices.

It is understood that sending an alarm may be either by conveying a signal or by stopping the transmission of an "OK" signal. The last option is in particular useful in that certain malfunctions of the device like e.g. a power failure device will be detected by the user.

Due to the fact that the present invention may take on diverse embodiments, it is possible to configure the present invention to monitor for inflammation, trauma or other conditions indicative of a problem with a skin mountable medical device. For example sensors can monitor for changes in skin characteristics at or near the area of insertion or in the vicinity of where the device is mounted to the skin. When the sensors detect a characteristic or change in characteristics indicative of a problem, such as inflammation at an injection site, a controller can send a signal to the user. Thus, the present invention may be an apparatus or method for detecting bodily reactions to the medical device as well as loss of engagement between the body and the wearable device or portion thereof.

In the above-described medical devices, the transcutaneous device may be a transcutaneous access device, the medical device further comprising a reservoir adapted to contain a fluid drug, and an expelling assembly adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the transcutaneous access device. In further embodiments the transcutaneous device may be in the form of a transcutaneous sensor device, the medical device further comprising processor means adapted to transmit and/or process data acquired via the sensor device.

The present invention provides numerous advantages to a patient using a medical device. In one embodiment, a patient is provided with a soft cannula (or other transcutaneous delivery device) to deliver medication below a skin surface. The cannula has some fiber optic-like properties and allows light to be transmitted and/or refracted thru the cannula. Light or a signal comprised of light with certain characteristics in the cannula can be monitored. A non-crimp condition will result in a specific observable characteristic in the light, such as intensity, or certain frequency or wavelength, but a crimped condition will cause a change in this monitorable characteristic and thus can be used to alert a user of a problem with the cannula. Of course, any measurable or monitorable property of a transcutaneous device that changes

upon improper insertion can be employed with the present invention to determine when improper insertion has occurred and the present invention is not limited to use of fiber optic properties of soft cannulas.

In a further aspect of the invention, a system comprises a soft catheter comprised of a light carrying polymer, a light source, such as a light emitting diode transmitted through the light-carrying (fiber-optic) polymer, and a sensor to detect the refraction range of the color at the end of the polymer. A detection of a light range within a certain spectrum will indicate if the catheter is blocked, e.g., crimped, allowing the system to then alert the user to the problem.

Another embodiment of the present invention utilizes the light carrying ability of the cannula to transmit light over its length and below the surface of the patient's skin. A sensor near the insertion site and located on or near the outer surface of the skin can detect light. If the cannula is not fully inserted or if it is crimped, the surface of the skin will be more illuminated than if the cannula is un-crimped and terminates at the proper depth below the skin. The sensor can thus indicate when crimping or improper insertion has occurred and the user can be warned. The cannula and sensor need not be visible to the user.

Thus, the present invention provides a method for detecting improper insertion of a transdermal device, the method comprising the steps of: (a) inserting a transdermal device through a skin surface, (b) transmitting a signal through the transdermal device, (c) monitor whether the transmitted signal is exiting into a patient at a predetermined depth below the skin surface of a patient, and (d) if the predetermined quantity of the signal is lost before exiting at the predetermined depth, notifying the user of an insertion problem.

A further method is provided for warning the user that a soft cannula is improperly inserted, the method comprising the steps of: (a) inserting a cannula out of sight of a patient, (b) monitoring a property of the cannula that changes upon improper insertion, and (c) when the monitoring indicates improper insertion, warning the patient.

In the context of the present application and as used in the specification and claims, the term circuitry covers any combination of electronic circuitry and associated components, e.g. sensors, suitable for providing the specified functionality, e.g. sensing properties, processing data and controlling memory as well as all connected input and output devices. The circuitry may comprise one or more processors or CPUs which may be supplemented by additional

devices for support or control functions. For example, the sensor means, a transmitter, or a receiver may be fully or partly integrated with the controller, or may be provided by individual units. Each of the components making up the circuitry may be special purpose or general purpose devices.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with references to the drawings, wherein

figs. 1-9 shows in perspective views the sequences of use for a first embodiment of a drug delivery device,

fig. 9A shows perspective view of the interior of a reservoir unit,

fig. 10 shows an embodiment of a skin-mountable medical device,

fig. 11 shows a further embodiment of a skin-mountable medical device,

fig. 12 shows a part of a yet further embodiment of a skin-mountable medical device,

figs. 13 and 14 shows first and second situations of use of a skin-mountable medical device comprising a soft cannula, and

fig. 15 shows an embodiment of a skin-mountable medical device.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical” or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

Firstly, with reference to figs. 1-12 an embodiment of a drug delivery device will be described focusing primarily on the directly user-oriented features. The transcutaneous device unit 2 comprises a transcutaneous device in the form of a hollow infusion needle and will thus in the following be termed a needle unit, however, the needle may be replaced with any desirable transcutaneous device suitable for delivery of a fluid drug. Correspondingly, the transcutaneous device may be in the form of a sensor and the second unit may comprise sensor means adapted to cooperate with the needle sensor.

More specifically, fig. 1 shows a perspective view of medical device in the form of a modular skin-mountable drug delivery device 1 comprising a patch-like needle unit 2 and a reservoir unit 5. When supplied to the user each of the units are preferably enclosed in its own sealed package (not shown).

The needle unit comprises a base portion 10 with a lower mounting surface adapted for application to the skin of a user, and a housing portion 20 in which a hollow infusion needle (not shown) is arranged. The needle comprises a first needle portion having a pointed distal end adapted to penetrate the skin of a user, and a second pointed end adapted to be arranged in fluid communication with the reservoir unit. In the shown embodiment the pointed end of the needle is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. Further, the needle is moveable between the extended position in which the pointed end projects relative to the mounting surface, and a retracted position in which the pointed end is retracted relative to the mounting surface. The needle unit further comprises user-gripable actuation means in the form of a first strip-member 21 for moving the pointed end of the needle between the initial and the second position when the actuation means is actuated, and user-gripable retraction in the form of a second strip-member 22 means for moving the pointed end of the needle between the extended and the retracted position when the retraction means is actuated. As can be seen, the second strip is initially covered by the first strip. The housing further comprises user-actuatable male coupling means 40 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means on the reservoir unit, this allowing the reservoir unit to be releasable secured to the needle unit in the situation of use. In the shown embodiment the base portion comprises a relatively rigid upper portion 11 attached to a more flexible adhesive sheet member 12 having a lower adhesive surface providing the mounting sur-

face *per se*, the adhesive surface being supplied with a peelable protective sheet. The base portion also comprises a ridge member 13 adapted to engage a corresponding groove on the reservoir unit.

The reservoir unit 5 comprises a pre-filled reservoir containing a liquid drug formulation (e.g. insulin) and expelling means in the form of an electronically controlled pump for expelling the drug from the reservoir through the needle in a situation of use. The reservoir unit has a generally flat lower surface adapted to be mounted onto the upper surface of the base portion, and comprises a protruding portion 50 adapted to be received in a corresponding cavity of the housing portion 20 as well as female coupling means 51 adapted to engage the corresponding hook members 31 on the needle unit. The protruding portion provides the interface between the two units and comprises a pump outlet and contact means (not shown) allowing the pump to be started as the two units are assembled. The lower surface also comprises a window (not to be seen) allowing the user to visually control the contents of the reservoir.

First step in the mounting procedure is to assemble the two units by simply sliding the reservoir unit into engagement with the needle unit (fig. 2). When the hook members properly engage the reservoir unit a "click" sound is heard (fig. 3) signalling to the user that the two units have been properly assembled. If desired, a visual or audible signal may also be generated. Thereafter the user removes the peelable sheet 14 to uncover the adhesive surface (fig. 4) where after the device can be attached to a skin surface of the user, typically the abdomen (fig. 5). Infusion of drug is started by gripping and pulling away the actuation strip 21 as indicated by the arrow whereby the needle is inserted followed by automatic start of the infusion (fig. 6). The needle insertion mechanism may be supplied in a pre-stressed state and subsequently released by the actuation means or the needle insertion may be "energized" by the user. A "beep" signal confirms that the device is operating and drug is infused. The reservoir unit is preferably provided with signal means and detection means providing the user with an audible alarm signal in case of e.g. occlusion, pump failure or end of content.

After the device has been left in place for the recommended period of time for use of the needle unit (e.g. 48 hours) – or in case the reservoir runs empty or for other reasons - it is removed from the skin by gripping (fig. 7) and pulling (fig. 8) the retraction strip 22 as indicated by the arrows which leads to retraction of the needle followed by automatic stop of drug infusion where after the strip which is attached to the adhesive patch is used to remove the device from the skin surface (fig. 9).

When the device has been removed the two units are disengaged by simultaneously depressing the two hook members 31 allowing the reservoir unit 5 to be pulled out of engagement with the needle unit 2 which can then be discarded. Thereafter the reservoir unit can be used again with fresh needle units until it has been emptied.

Fig. 9A shows the reservoir unit with an upper portion of the housing removed. The reservoir unit comprises a reservoir 560 and an expelling assembly comprising a pump assembly 500 and control and actuation means 580, 581 therefore. The pump assembly comprises an outlet 322 for connection to a transcutaneous access device and an opening 523 allowing an internal fluid connector to be actuated, this providing a fluid communication between the pump assembly and the reservoir. The reservoir 560 is in the form of prefilled, flexible and collapsible pouch comprising a needle-penetratable septum adapted to be arranged in fluid communication with the pump assembly, see below. The shown pump assembly is a mechanically actuated membrane pump, however, the reservoir and expelling means may be of any suitable configuration. The control and actuation means comprises a pump actuating member in the form of a coil actuator 581 arranged to actuate a piston of the membrane pump, a PCB or flex-print to which are connected a microprocessor 583 for controlling, among other, the pump actuation, contacts 588, 589 cooperating with the contact actuators on the needle unit, signal generating means 585 for generating an audible and/or tactile signal, a display (not shown) and an energy source 586. The contacts are preferably protected by membranes which may be formed by flexible portions of the housing.

The embodiments described with reference to figs. 10-14 are unitary, however, the same technical features may be implemented in a divided device of the type shown in figs. 1-9.

Fig. 10 shows medical device 100 comprising a mounting surface 101 adapted for application to a skin surface 102 of the subject, and a transcutaneous device 110 adapted to be arranged in the subcutis 103 a subject. The transcutaneous device may be in the form of a transcutaneous drug delivery device, e.g. a needle or a soft cannula, or a sensor device. In the shown embodiment the transcutaneous device is adapted to conduct an electric current. The device further comprises first capacitor means in the form of a capacitor plate 120 associated with the mounting surface. The capacitor of this and any of the following embodiments may be provided by any conducting surface, e.g. a thin metal foil or a conducting paint. The second capacitor “plate” is established by the transcutaneous device when it is arranged in

the subcutis of the subject, the subcutaneous tissue operating as a low impedance plan, whereby a capacitor is established between the capacitor plate and the subcutis area positioned there below. The device also comprises a voltage AC source 131 connected to the capacitor plate and the transcutaneous device, a resistor 132 arranged there between, and detecting circuitry for processing signals from the capacitor and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected. Such a condition could be that the device had been removed fully or partly from the skin surface or that the transcutaneous device had been pulled out of the subcutis of the subject, all conditions that to a certain degree would result in a measurable change in capacitance of the system established by the two capacitor plates. An alternative measuring system could be a current AC generator applied between the capacitor plate and the transcutaneous device and a circuit to measure the AC voltage over this described capacitor system.

In the shown embodiment the transcutaneous device is in the form of a transcutaneous access device (e.g. needle or soft cannula) just as the device comprises a process unit 140 in the form of a reservoir 141 adapted to contain a fluid drug, and an expelling assembly 142 adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the transcutaneous access device.

Example

Z(C-patch) is the impedance for the patch-subcutis capacitor at a given AC frequency. i(f) is the generator current at the given AC frequency described in the alternative measuring system above. V (X-threshold) are different limits for a given detection scheme of the voltage difference measured across the patch-subcutis capacitor.

- Z(C-patch) * i(f) < V(OK-threshold) means that the patch and cannula are OK.
- V(OK-threshold) < Z(C-patch) * i(f) < V(Not-OK-threshold) means that the patch and/or cannula properly is becoming detached.
- V(Not-OK-threshold) < Z(C-patch) * i(f) means that the patch and/or cannula has become detached.

Indeed, thresholds for different levels of detachments may be determined, e.g. 25%, 50% or 75%. Such percentages do not necessary indicate that the patch has become e.g. 25% loose as the capacitance will drop with the distance between the two capacitor plates, e.g. the

greater an area of the device has become loose and the greater the displacement from the skin surface, the greater the difference in capacitance.

In an alternative embodiment shown in fig. 11, a medical device 200 comprises first and second capacitor plates 221, 222 associated with the mounting surface, whereby a capacitive circuit can be established when the mounting surface is arranged on a skin surface.

Fig. 12 shows in partial representation a medical device 300 comprising a patch unit 310 and a housing unit 320 adapted to be coupled to each other, the patch unit comprising a mounting surface 301 and the capacitor plate(s) 320, and the housing unit comprising the circuitry (see fig. 11). Instead of using a galvanic contact between the circuitry and the capacitor plate, the circuitry is coupled to the capacitor plate(s) by a capacitive coupling 325.

Fig. 15 shows a medical device 400 comprising a patch unit 410 and a housing unit 420 adapted to be coupled to each other, the patch unit comprising a mounting surface 401 adapted for application to a skin surface of a subject, and a transcutaneous device 415 adapted to be arranged subcutaneously in a subject. The lower surface of the patch unit comprises two openings 411, 412. In the shown embodiment the housing unit comprises two sensors 431, 432, arranged in alignment with the two openings, and thereto connected circuitry 430 for processing signals from the sensors and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected. The shown sensors 431, 432 may represent sensors “per se”, e.g. temperature or mechanical sensors, or they may represent a part of a sensor, e.g. the inlet of an optical guide system, the remaining portion of the sensor being located centrally, e.g. associated with the processing circuitry as described below for a camera system. Alternatively the medical device may be of unitary construction as in the fig. 10 embodiment, just as one or more than two sensors may be used.

The sensor means are adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject, e.g. the sensors may be capable of detecting characteristics indicative of inflammation, an optical property of skin, or other conditions indicative of an insertion site reaction. Alternatively, the sensors may be adapted to monitor a characteristics indicative of the position of the medical device relative to a skin surface, e.g. the sensor may be capable of sensing temperature, distance (e.g. measuring the distance between the lower surface of the device and the skin surface, e.g. using

echo determination), position (e.g. the acoustic properties (e.g. the natural frequency) of the device will change depending on how the device is attached to the skin, this being detectable by e.g. a sound generator and detector), motion pattern (e.g. a changed motion pattern being indicative of the device having become loose relative to the skin), or a contact force between the apparatus and a skin surface (e.g. a spring actuated sensor).

Further types of sensor arrangement may be used in the context of the present invention. A lower adhesive surface portion of a flexible patch foil may have an area with a relatively weak adhesive to which an optical marker is attached, the optical marker having a lower surface with an adhesive e.g. corresponding to adhesive on the main portion of the patch foil. The patch foil above the marker has an optical opening which initially is covered (from below) by the marker. In case the patch becomes (partly) detached and able to move relative to the marker, the optical opening will no longer be closed, which condition can be detected by an optical sensor and the information used to detect early disengagement of the patch. Instead of an optical system, the marker and the patch may form first and second portions of an electrical contact. In order to remove the marker from the skin after use, the marker may be attached to the patch foil by e.g. a string or other means.

A portion of the adhesive patch foil may be applied to a skin surface in a stretched condition, this allowing the initially stretched portion to contract in case the stretched portion disengage from the skin. When a marker, e.g. optical, electrical, or magnetic, is attached to such a portion, then the relative movement between such a marker and the remaining device can be detected and used to evaluate disengagement of the patch from the skin. Such a stretched portion may e.g. be arranged around a transdermal device where correct attachment of the device to the skin is most important. Correspondingly, a given patch may comprise two or more detections systems (each comprising sensors of any suitable type), one for the area surrounding a transdermal device, and one or more for the remaining portion of the device.

Instead of a mechanical contact indicating whether or not a given portion of the device is in contact with a skin portion, a thermal sensor system may be used. For example, a thermal actuator may apply a small amount of energy to the skin surface to which it is intended to be in contact with. When the thermal actuator is in contact with the skin there will be almost no temperature raise in the tip of the actuator because of the specific heat capacity of the skin whereas the temperature in the actuator tip will raise if the skin is not receiving the heat cur-

rent. As follows, in case the thermal actuator is not in contact with a skin surface, the thermal sensor should register a raise in temperature.

In a further embodiment of the present invention, a medical device may include a series of electrical contacts that are mounted to a skin contacting surface of a medical device. The device can be affixed to a skin surface with an adhesive. The adhesive may be applied directly to the skin contacting surface or may be a two-sided tape or the like. The surface may have several portions. Between the several portions of the surface, holes or openings may be interspersed. A first contact may be connected to a first portion of the skin mounting surface, a second contact may be connected to a second portion of the skin mounting surface, and the contacts may be positioned across an opening. In some embodiments, a cannula, needle, or other transcutaneous device, is mounted through the one of the surfaces. When the two surfaces are substantially coplanar, the contacts remain engaged with each other and form a closed circuit. The two surfaces need not be perfectly planar, as any given surface is rarely truly planar. Indeed, most skin surfaces are not perfectly planar but nonetheless may still have portions that are substantially planar. However, when the two surfaces become substantially non-coplanar, the contact between them disengage and an open circuit is formed.

A controller, such as a processor based controller, can be used to send a signal or record information relating to the various states of the circuit formed by the contacts. As a result of the change of state of the circuit, a signal can be sent to the patient to warn of possible skin disengagement.

The same embodiment can be used to detect when the cannula has moved out of engagement with the skin surface. Here, a cannula is mounted through a surface. A contact connected to this surface can be used to detect when the two surfaces are substantially non-coplanar, thus indicating that one of the surfaces has moved away from the skin surface. As the circuit in this embodiment only shows relative movement, it may not be able to differentiate between cannula disengagement and loss of adhesion of the remainder of the other surface. The other skin mounting surfaces may e.g. be monitored to determine that they are in proper contact with the skin surface. If this is the case and it is determined that two surfaces are in skin contact, then relative movement of surfaces would then indicate that the cannula has become disengaged or is in danger of disengaging.

It should be understood that not all portions of the skin contacting surface need to have adhesive. For example, it may be desirable to omit the adhesive on one of the above-described sections.

Other variations may also me employed with the present invention. The cannula does not need to be surrounded by a skin contacting surface. In some such embodiments it may be desirable to connect a portion of a sensor directly to the cannula. This arrangement allows for detection when the cannula moves relative to a surface on the device, such as is the case when the cannula is improperly inserted or fails to be completely inserted.

Those skilled in the art will recognize that it would be virtually impossible to list every variant that is with in the scope of the present invention. Moreover, the various aspects of the various enumerated embodiments may be combined to create more robust systems and the sensor systems described herein are merely examples of some of the capabilities the present invention may have. Clearly the present invention allows for extremely robust and sophisticated monitoring of patient-device interaction.

For example – and without limitation – the present invention may employ sensors that detect inflammation or site reactions to a wearable device. This is particularly useful in detecting injection site reactions. In some embodiments, detectors are placed in or under the adhesive securing the transdermal device to the skin. The detectors may be arranged such that one of the detectors may be near an insertion site whereas other detector or reference detector is located a distance away from the insertion site. A monitoring device may monitor the sensors and compares the detected values for differences both at a given time and as a function of time. For example inflammation may be detected by changes in dermal properties set forth in the table below.

PROPERTY	**EXEMPLARY DETECTION METHOD/SYSTEM**
Chemical Properties	Examples such as pH or H_2O_2 may be detected by electrochemical means and/or by use of various markers. E.g. an IS-FET mounted on top of the needle measuring a chemical substance in dermal changing due to inflammation.
Temperature	Detectors may be thermal sensing elements e.g. mounted in a Wheatstone bridge. However, meas-

	urement of the skin colour may be an alternative detection strategy. The temperature rise is due to the fact that the skin is cooler than the core of the body (around 30°C due to thermal losses to the surroundings). If the capillary vessels expand this will increase the flow of 37°C blood to the surface and thus increase the temperature
Colour	Changes in spectral absorption may be detected by optical methods (figure 2). The change in skin colour is due to the fact that the capillary vessels expands, thus making the blood more "visible".
Electrical	It is believed that the impedance of the system patch/skin will change due to inflammation. The change may either be in the resistance or in the complex impedance. Conductance can be measured by means placed on the needle. Reactance (capacitance) can be measured in dermal. A needle connects to subcutaneous space which is the one plate in a plate capacitor. The other plate is placed in the device. Dermal is the dielectricum changing its parameter and size during inflammation
Mechanical properties due to swelling	When the tissue swells the tissue becomes stiffer. This can be measured by measuring the mechanical stiffness of the tissue using a mechanical gauge. Due to swelling the skin will locally expand (figure 3). This can be measured by detection of mechanical deformation of the adhesive secured to the skin. The deformation can e.g. be measured using a strain gauge e.g. at an elastic part of the upper part of the needle.
Acoustical properties	When inflammation occurs the acoustic properties at the insertion site changes. The change is partly due to changes in the acoustic properties of the tissue and

	partly due to a changed coupling between the needle and the surrounding tissue.
Increased neural activity	Measurement of the neural activity by probing e.g. using the needle as conductor. If pain signals are transmitted from the synapses this can be detected.

With reference to the above-described embodiments, sensors have been described which may be used to detect a visual chance in skin appearance e.g. around the insertion site for a transcutaneous device.

However, it may still be desirable to visually check a skin condition and thus inspect the infusion site in order to control the correct insertion of the catheter in the tissue - both when inserted and later during use. Users may also wish to control the skin for undesirable reactions to the catheter or to the adhesive. Because the infusion set is placed far from the eyes, normally on the abdomen, this inspection is difficult for many people especially if they are obese as many e.g. type 2 diabetics are.

Thus, in a further aspect of the invention two principal solutions to the problem is proposed. (i) Instead of putting the eyes to the infusion site the image of the infusion site is put to the eyes. (ii) Instead of using the eyes and brain to see and analyze the problem it is recorded and analyzed artificial and only the result is transferred directly or indirectly to the user. The two solutions can also be combined.

The image can be acquired and displayed e.g. in the following ways: (a) By a camera function recording the image at the infusion site and displaying it on a device that can be taken to the eyes – the recording is either as one or more snapshots or continuously. (b) By an image guiding system based on reflections as in an endoscope where one end is at the infusion site and the other end transferring the image to the eyes. (c) Based on light sensitive film as used in cameras. The film is exposed and the developed image taken to the eyes.

The camera function/part and the displaying part could be the same device, e.g. handheld as in a cell phone. If the infuser already utilizes a remote controller the camera part and displaying part could be build into this device. The camera function/part could also be an integrated part of the infuser attached to the user. For example, a portion of an ASIC may comprise a C-MOS image sensor (or otherwise be associated with an image sensor), the images being

transferred to the ASIC by an optical guide system, e.g. an optical fiber or a mirror system. In such a system the optical guide system and an image sensor could be regarded a sensor means providing information to the above-described circuitry for processing signals from a sensor means. The image could then be transferred to the displaying device either by moving a data memory, by data channels as e.g. a wire or wirelessly. Additional analyzing algorithms can be applied on the acquired images in order to achieve information from the images, e.g. pattern recognition techniques, spectral sensitivities, time dependent development, averaging or zooming. Additional recording means can be applied on the recording environment in order to achieve information from the images, e.g. certain spectral illumination of the spot. Instead of or supplementary to transferring the images to the user the processed information or the result hereof can be transferred to the user. The analyzing could take place continuously, regularly or on user demand. The analyzing could take place without the user's awareness.

A primary advantage of such a camera equipped system would be the increased ability for the user to monitor and/or inspect the infusion site including the catheter, hereby avoiding hazards related to malfunction of the infuser, transdermal device, adhesive and unintended skin reactions. Build-in algorithms to evaluate/analyze the images will also increase this possibility, especially if they operate continuously.

With reference to figs. 13 and 14 a further aspect of the present invention will be described.

As is shown in fig. 13, a skin mountable infusion device 600 has skin mounting surface 601 and a soft cannula 610 that protrudes thru the skin mounting surface. The soft cannula is in fluid communication with a fluid delivery assembly 620 (comprising an expelling assembly and an associated reservoir) and may be inserted through a skin surface 602. WO 03/090509, which is hereby incorporated by reference, discloses an insertion scheme for a cannula based delivery device. Alternatively the cannula may be fixed relative to the mounting surface of a delivery device i.e., e.g. as in a traditional infusion set. Of course other schemes may be used and the user does not have to observe actual insertion. A light source 631, such as an LED is located near, adjacent to, on the surface of, or in any other manner that allows light to be inserted into the cannula. For example it may, in some embodiments, be possible to have the light source within the medication reservoir, or integral with it in a manner that allows the cannula to be illuminated. A sensor 632 is located such that it can detect light within the cannula. When the cannula is in an un-crimped state, as is the case in

fig. 13, the light will have a certain characteristic, such as color, intensity, e.g. when the cannula becomes crimped, as is shown in fig. 14, the crimp or kink 611 causes he characteristic of the light to change and this change will be detected by the sensor 632. The device further comprises circuitry 633 for processing signals from the sensor and for indicating that a predetermined condition associated with the cannula has been detected, e.g. a certain degree of crimping, kinking or other damage. The circuitry may be connected to an alarm 635 that warns the patient, or a circuit interfaced with an alarm device. Thus, the patient does not need to observe the insertion site to know that there is a problem with the cannula insertion.

Other arrangements are possible (such as the light source being in the reservoir or integrated into the reservoir wall). Thus, the invention is not limited to one specific location of a light source and one location of a sensor. In fact, the invention is not limited to the use of light to detect crimping. Any suitable property of the cannula indicative of crimping can be used with the present invention, e.g., vibration by a piezo actuator.

In an alternative embodiment a sensor is located near the skin surface where the cannula penetrates the skin of the subject. In an un-crimped and properly inserted position, the light exits the cannula at a depth D below the skin surface. If the cannula is crimped or improperly inserted, the light will exit at a kink or exit the end of the cannula at a depth d, which is closer to the skin surface. The sensor can detect this and then cause the alarm to warn the patient.

While the present invention is described above with respect to skin wearable medication delivery devices, it is equally applicable to other devices. For example, the system could be implemented in any device especially those comprising a soft catheter, including skin-mounted infusion pumps, insertion sets, CGM sensors, and so forth. In fact, the cannula need not necessarily be a medication delivery apparatus, but could instead be some other transdermal device, such as a probe, sensor or the like. Moreover, the fiber optic nature of the cannula described is but one way to practice the present invention. Other properties, such as mechanical, chemical, etc. can be monitored for changes that occur due to improper insertion.

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CLAIMS

1. A medical device (100) comprising:
- a mounting surface (101) adapted for application to a skin surface (102) of a subject,
- a transcutaneous device (110) adapted to be arranged subcutaneously in a subject,
- sensor means (110, 120) adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject, and
- circuitry (131, 132, 133) for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected,
- wherein the sensor means comprises first and second capacitor means (110, 120).

2. A medical device as in claim 1, wherein the transcutaneous device (110) is adapted to conduct an electric current, the first capacitor means is a capacitor plate (120) associated with the mounting surface, and the second capacitor means is established by the transcutaneous device when it is arranged in the subcutis (103) of the subject, whereby a capacitor is established between the capacitor plate and the subcutis area positioned there below.

3. A medical device as in claim 1, wherein the first and second capacitor means are first and second capacitor plates (221, 222) associated with the mounting surface, a capacitive circuit being established when the mounting surface is arranged on a skin surface.

4. A medical device as in claim 2 or 3, comprising a patch unit (310) and a housing unit (320) adapted to be coupled to each other, the patch unit comprising the mounting surface and the capacitor plate(s) (320), and the housing unit comprising the circuitry.

5. A medical device as in claim 4, wherein the circuitry is coupled to the capacitor plate(s) by a capacitive coupling (325).

6. A medical device (400) comprising:
- a mounting surface (401) adapted for application to a skin surface of the subject,
- a transcutaneous device (415) adapted to be arranged subcutaneously in a subject,
- sensor means (431, 432) adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject, and

- circuitry (430) for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected,
- wherein the sensor means is adapted to monitor at least one skin characteristics indicative of a skin condition at a given location.

7. A medical device as in claim 6, wherein the sensor is capable of detecting characteristics indicative of inflammation, an optical property of skin, or other conditions indicative of an insertion site reaction.

8. A medical device (400) comprising:
- a mounting surface adapted for application to a skin surface of the subject,
- a transcutaneous device adapted to be arranged subcutaneously in a subject,
- sensor means adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject, and
- circuitry for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected,
- wherein the sensor means is adapted to monitor a characteristics indicative of the position of the medical device relative to a skin surface.

9. A medical device as in claim 8, wherein at least one sensor senses either temperature, distance, motion pattern, or a contact force between the apparatus and a skin surface.

10. A medical device as in any of claims 6-9, comprising at least two sensors (431, 432), the circuitry being adapted to detect a given condition based on a comparison between the at least two sensors.

11. A medical device as in any of claims 6-9, comprising at least one sensor (431), the circuitry being adapted to detect one or more given conditions based on an analysis of time-dependent variations of the measured condition(s).

12. A medical device as in any of claims 6-11, wherein the skin mountable surface has one or more openings (411, 412) formed therein and wherein one or more sensors span a portion of the one or more openings.

13. A medical device as in any of claims 6-11, comprising a patch unit and a housing unit adapted to be coupled to each other, the patch unit comprising the mounting surface, and the housing unit comprising at least one sensor and the circuitry, wherein the skin mountable surface has one or more openings formed therein and wherein one or more sensors span a portion of the one or more openings.

14. A medical device as in any of the previous claims, wherein the transcutaneous device is a transcutaneous access device, the medical device further comprising:

- a reservoir (141) adapted to contain a fluid drug, and
- an expelling assembly (142) adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the transcutaneous access device.

15. A medical device as in any of claims 6-13, wherein the transcutaneous device is in the form of a transcutaneous sensor device, the medical device further comprising processor means adapted to transmit and/or process data acquired via the sensor device.

16. A medical device as in any of the previous claims, comprising image-generating circuitry.

17. A medical device as in claim 16, further comprising a light-guide for transmitting an image of an object located outside the medical device to the image-generating circuitry.

18. A medical device as in claim 17, wherein the image-generating circuitry is associated with the circuitry for processing signals from the sensor means.

19. A system for detecting improper insertion of a transdermal device, the system comprising:

- a transdermal device (610) having a property that changes when the transdermal device is improperly inserted,
- a monitoring means (631, 632) for monitoring the property, and
- a circuit (633) for sending a signal indicating improper insertion when the means monitoring a change in the property detects a change in the property.

20. The system of claim 19, wherein the transdermal device is capable of transmitting or refracting light and wherein the property being monitored is an optical property.

21. The system of claim 20, wherein the system comprises a light source (631) for transmitting light through the transdermal device, and the monitoring means comprises a light detection sensor (632).

22. The system of claim 21, wherein the transdermal device is a soft cannula and the property being monitored is a fiber optic property of the cannula which changes when the cannula is improperly inserted due to cannula crimping.

Fig. 1

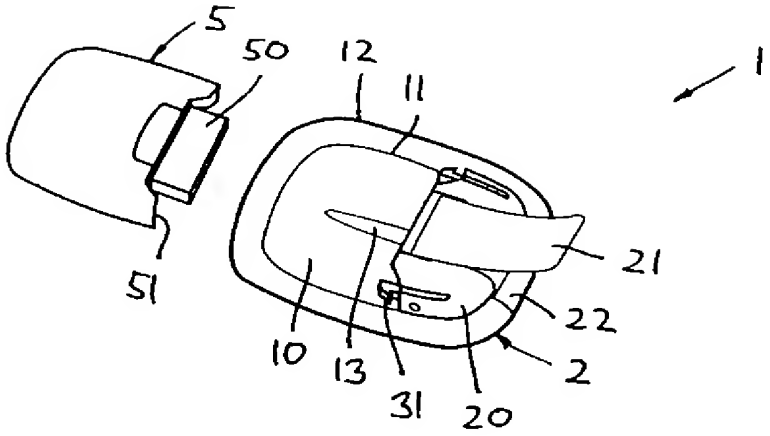


Fig. 2

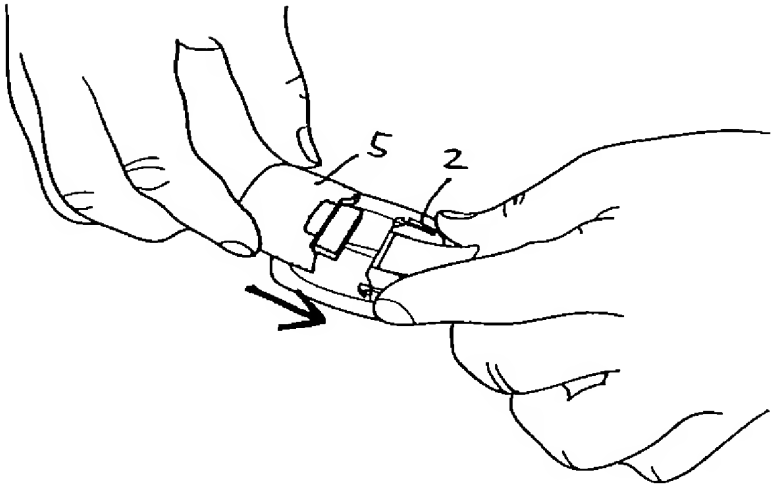


Fig. 3

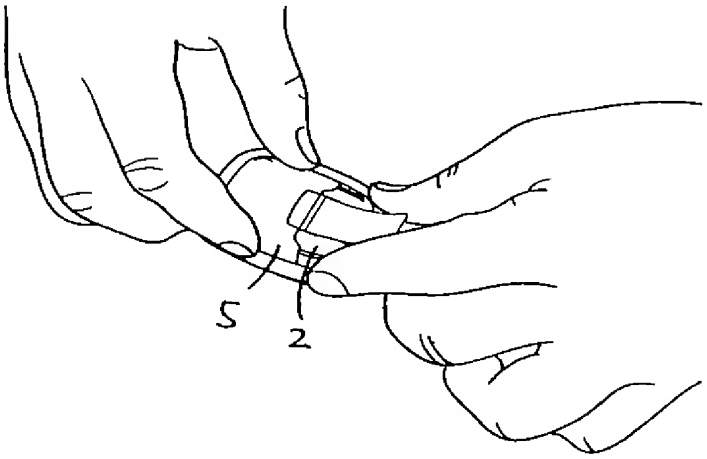


Fig. 4

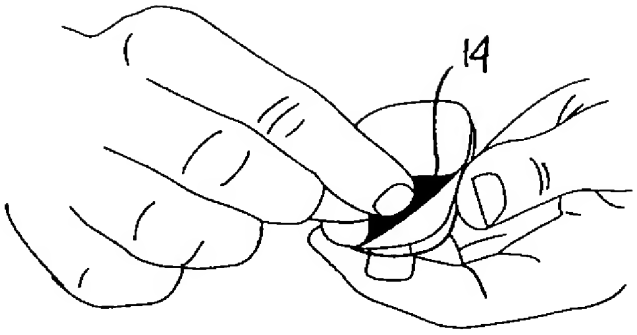


Fig. 5

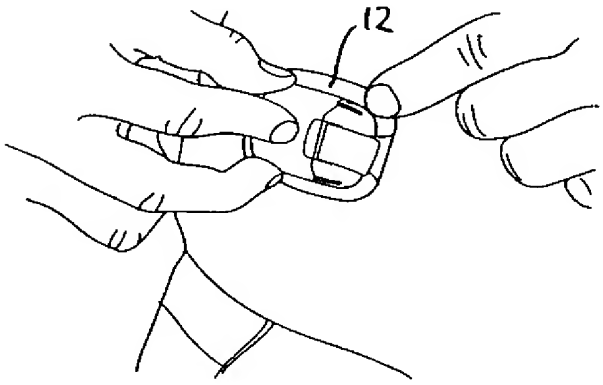


Fig. 6

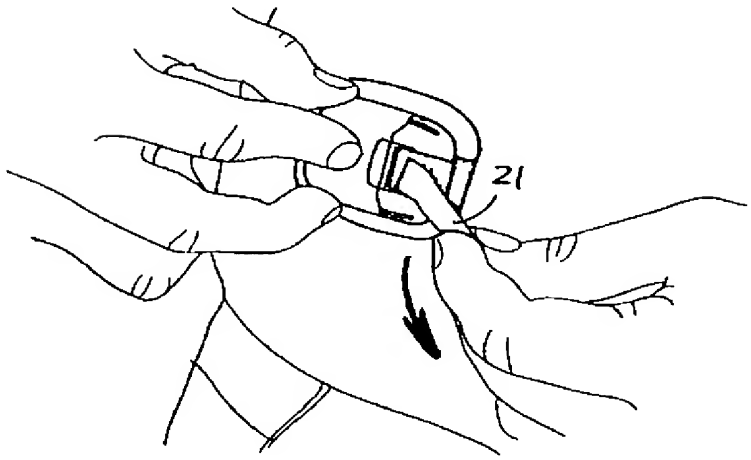


Fig. 7

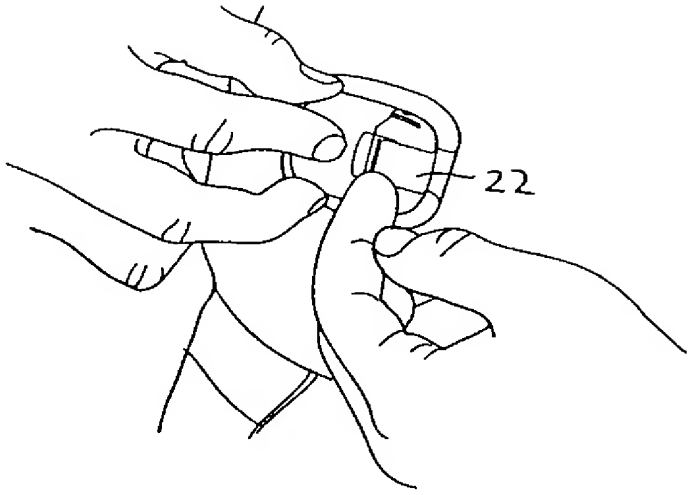


Fig. 8

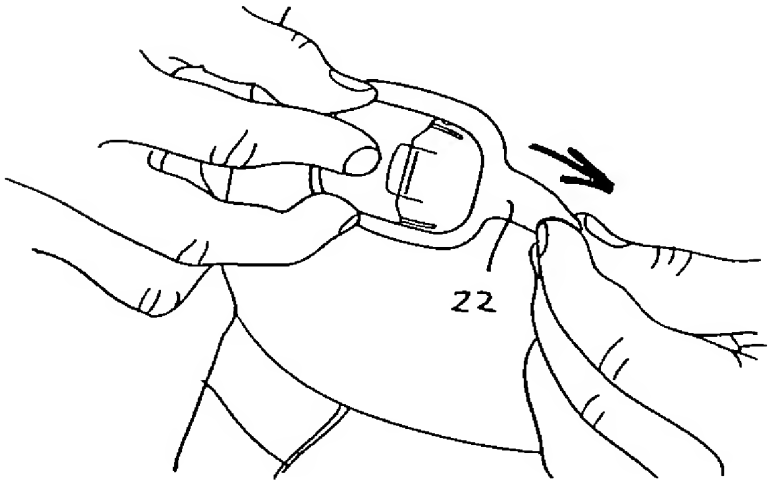


Fig. 9

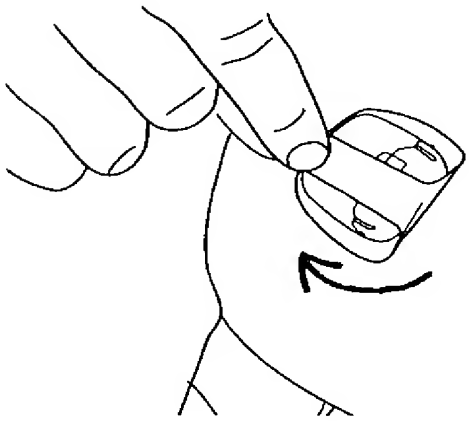


Fig. 9A

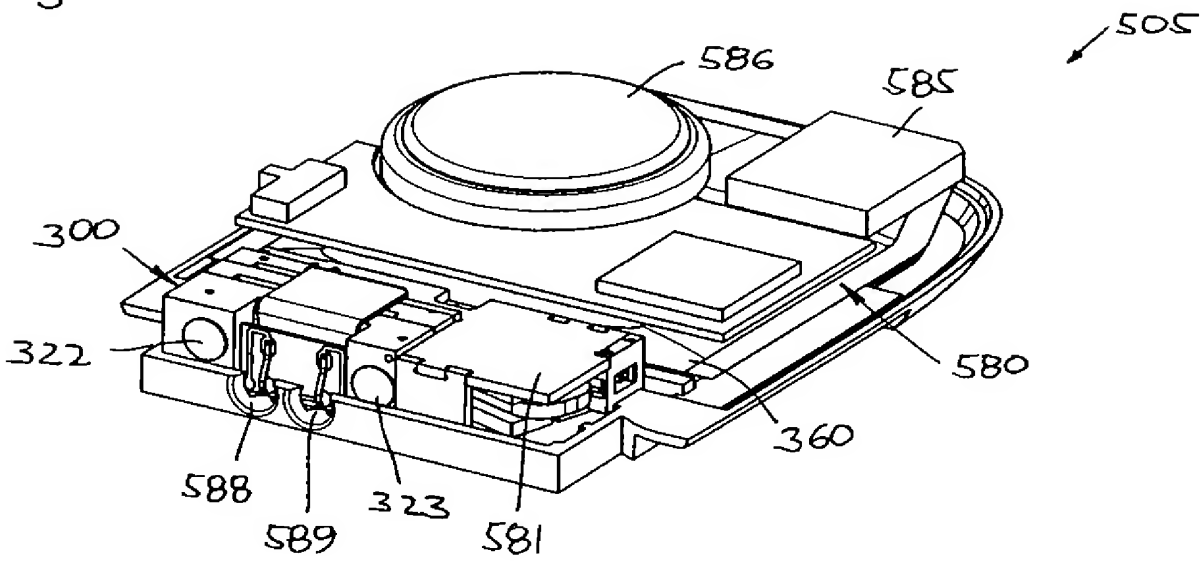


Fig. 10

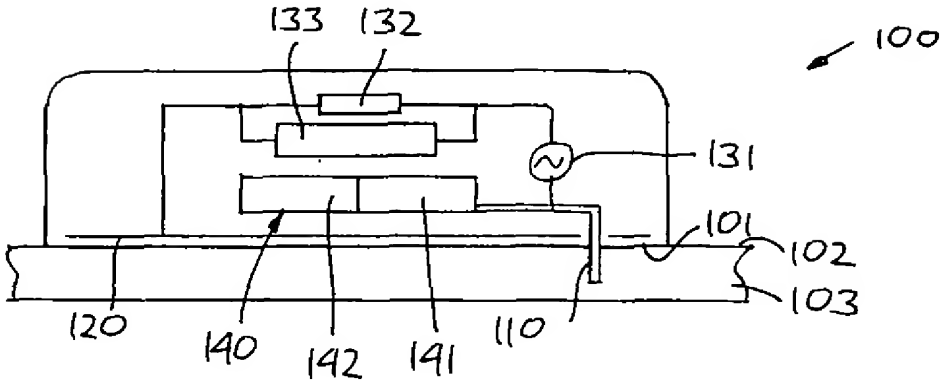


Fig. 11

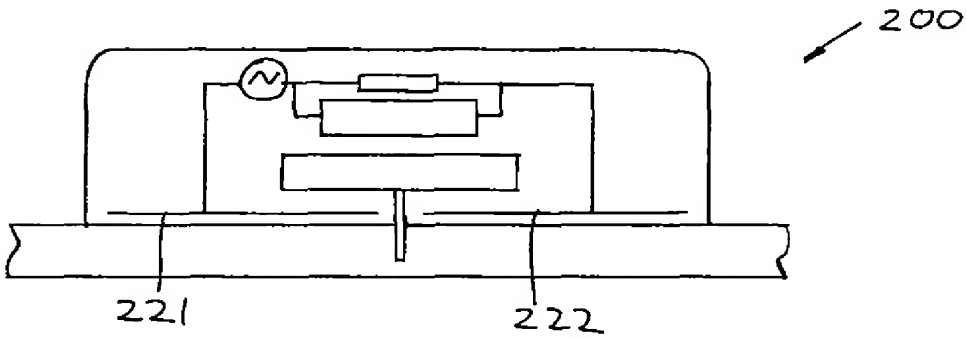


Fig. 12

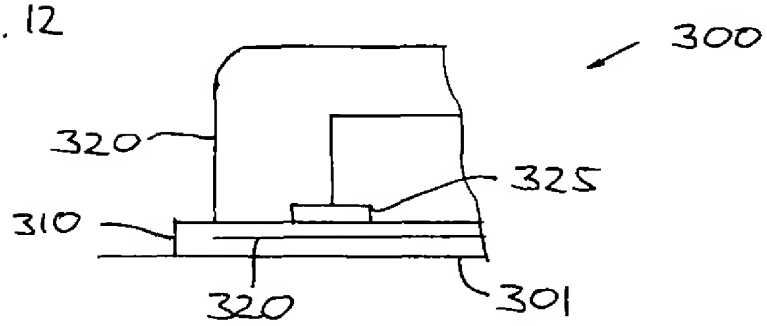


Fig. 13

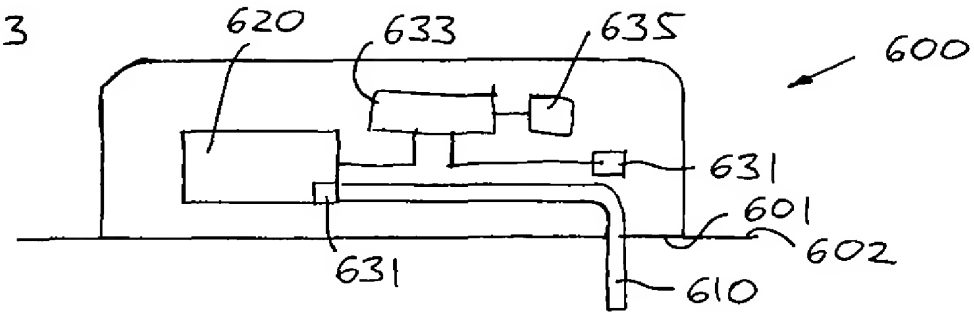


Fig. 14

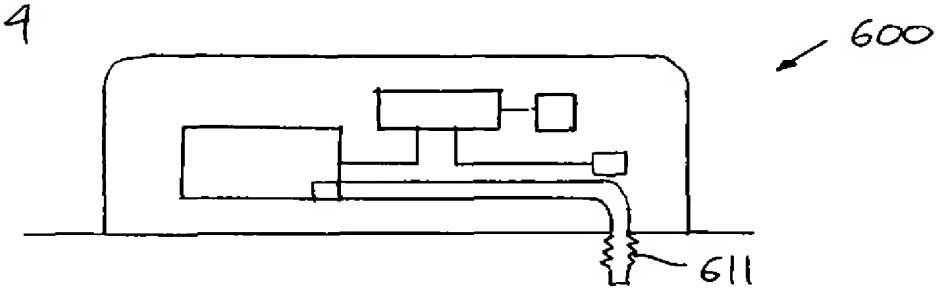
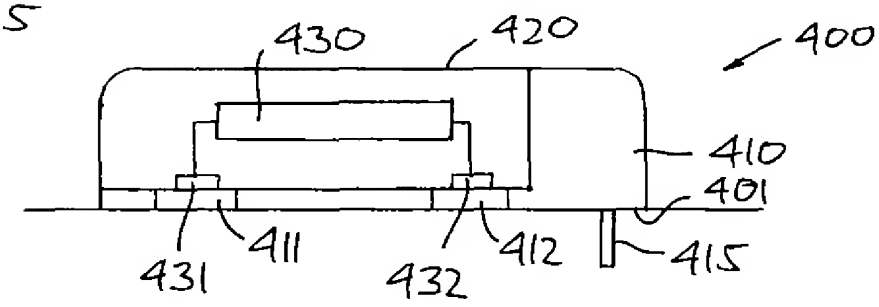


Fig. 15



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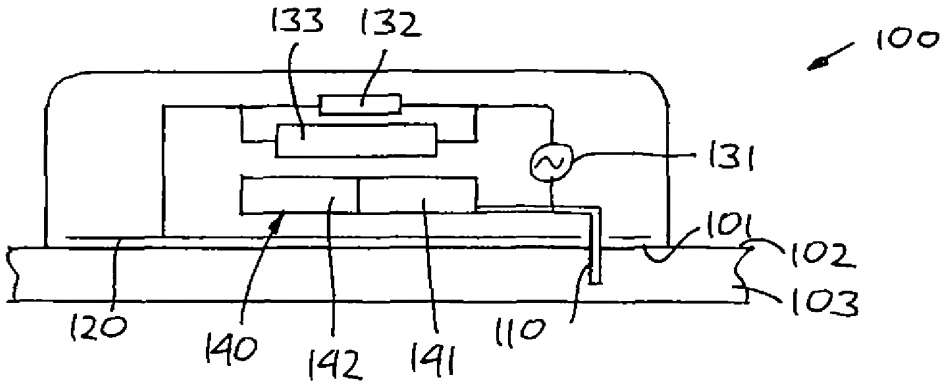
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
22 February 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SENSOR SYSTEM AND METHOD FOR DETECTING PROBLEMS WITH MOUNTING OF SKIN MOUNTABLE MEDICAL DEVICES



(57) Abstract: The invention relates to skin mountable medical devices adapted to ensure that the device or components thereof are properly in place with respect to the patient's body. In a specific aspect a medical device is provided comprising a mounting surface adapted for application to a skin surface of the subject, a transcutaneous device adapted to be arranged subcutaneously in a subject, and sensor means adapted to detect a property that can be indicative of a problematic condition relating to the interface of the device with the subject. The device further comprises circuitry for processing signals from the sensor means and for indicating that a predetermined condition associated with the interface of the device with the subject has been detected, and wherein the sensor means comprises first and second capacitor means.

WO 2006/067217 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2005/057105

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0424 A61B5/053 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/009131 A1 (VAN ANTWERP WILLIAM P ET AL) 9 January 2003 (2003-01-09)	1-5,8-15
A	paragraph [0040] - paragraph [0042]; figures 1-10	6,7, 16-22
Y	paragraph [0075] - paragraph [0076]	6,7, 16-22
X	US 2002/123740 A1 (FLAHERTY J. CHRISTOPHER ET AL) 5 September 2002 (2002-09-05)	1,8
A	paragraph [0013] - paragraph [0023]; figures 1-18	2-7,9-15
Y	paragraph [0055] - paragraph [0066]	6,7, 16-19

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2006	30/10/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neef, Tatjana

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2005/057105

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/026726 A (NOVO NORDISK A/S) 3 April 2003 (2003-04-03)	1-5, 8-15, 19-22
X	page 6, line 9 - page 18, line 34; figures 1-7 page 26, line 32 - page 27, line 11	6,7
X	US 2002/198483 A1 (WARIAR RAMESH ET AL) 26 December 2002 (2002-12-26)	1,3,5,8, 9
A	paragraph [0008] - paragraph [0039]; figures 1-3 paragraph [0061] - paragraph [0066]	2,4,6,7, 10-22
A	EP 0 778 000 A (OHMEDA INC; DATEX-OHMEDA, INC) 11 June 1997 (1997-06-11) column 2, line 8 - column 4, line 26; figures 1-3	1-18
A	US 4 295 475 A (TORZALA ET AL) 20 October 1981 (1981-10-20) column 2, line 8 - line 51; figure 1	1-18
A	US 2003/139656 A1 (KIANI MASSI E ET AL) 24 July 2003 (2003-07-24) paragraph [0030] - paragraph [0037]; figures 1-6 paragraph [0005] - paragraph [0007]	1-18
X	US 6 560 471 B1 (HELLER ADAM [US] ET AL) 6 May 2003 (2003-05-06)	1,3-9, 13-19
Y	column 2, line 14 - column 3, line 56; figures 1-28 column 7, line 30 - column 9, line 41 column 15, line 15 - column 18, line 21 column 23, line 29 - column 25, line 17 column 27, line 59 - column 62, line 51	19
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A	page 1, left-hand column, line 1 - page 4, left-hand column, line 17; figure 1	1-5,8-19
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2005/057105

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/069714 A1 (WIGLEY FREDRICK M [US] ET AL) 10 April 2003 (2003-04-10) paragraph [0006] - paragraph [0028]; figures 1-4	6,7
Y	US 6 397 099 B1 (CHANCE BRITTON [US]) 28 May 2002 (2002-05-28) column 2, line 15 - column 9, line 35; figures 1-6	16-18
Y	WO 99/07277 A (BOEHRINGER MANNHEIM GMBH [DE]; FRAUNHOFER GES FORSCHUNG [DE]; HAAR HAN) 18 February 1999 (1999-02-18)	6,7, 16-22
A	page 5, last paragraph - page 28, last paragraph; figures 1-18	1-5,8-15
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A	paragraph [0007] - paragraph [0036]; figures 1-13	6,7,9, 12-14, 16-18, 20-22
X	US 2002/065481 A1 (CORY JOAN M [US] ET AL) 30 May 2002 (2002-05-30)	19
A	paragraph [0010] - paragraph [0062]; figures 1-8	20-22
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A	page 1, line 12 - page 3, line 23 page 5, line 1 - page 8, line 23	20-22
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2005/057105

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5,8-15

   medical device mounted on skin surface, having a transcutaneous device, sensor means detecting a problematic condition relating to the interface of the device with the subject, monitoring the position relative to the skin surface

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2. claims: 6,7

   medical device mounted on skin surface, having a transcutaneous device, sensor means detecting a problematic condition relating to the interface/contact of the device with the subject, with the sensor monitoring a skin condition at a given location

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3. claims: 1,16-18

   medical device mounted on skin surface, having a transcutaneous device, sensor means detecting a problematic condition relating to the interface of the device with the subject, comprising image-generating circuitry

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4. claims: 19-22

   System detecting improper insertion of a transdermal device, by monitoring a property of the transdermal device that changes when the transdermal device is improperly inserted

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2005/057105

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Information on patent family members

International application No
PCT/EP2005/057105

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